JAN 2 3 2006

K051677

510(K) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA1990) and with 21 CFR Part 807.92

1. Name & Contact Information of Manufacturer

   Hitachi Chemical Diagnostics
   630 Clyde Court, Mountain View, CA 94043
   (650) 961 – 5501

2. Contact Person

   Emi Zychlinsky, Ph.D.
   VP of R&D

3. Establishment Registration Number

   2936856

4. Product Name

Proprietary Name:	OPTIGEN® Allergen-Specific IgE Assay System
Common Name:	Chemilumnescent Immunoassay for the detection of specific allergens
Classification Name:	System, Test, Radioallergosorbent (RAST) Immunological

5. Product Classification

Product Name	Product Code	Class	CFR
OPTIGEN® Allergen-Specific IgE Assay (20 allergens)	82 DHB	II	866.5750
OPTIGEN Positive Allergy Control Reagent	82DGC	II	866.5510
OPTIGEN Negative Allergy Control Reagent	82DGC	II	866.5510

6. Substantial Equivalence to:

   Assay
   a. Hitachi Chemical Diagnostics, CLA Allergen-Specific IgE Assay – Latex Allergen K82 (K030590)
   b. Pharmacia, Inc., UniCAP Specific IgE Assay (K962274)

7. Device Description

   a. The OPTIGEN® Allergen-Specific IgE Assay is a solid phase in vitro test used for the semi quantitative determination of circulating allergen-specific IgE antibodies to multiple allergens simultaneously in human serum.

8. Intended Use

   The OPTIGEN assay is an *in vitro* test, which provides a semi quantitative measurement of circulating allergen specific IgE antibodies in human serum. The OPTIGEN assay is intended to assist in the clinical diagnosis of IgE-mediated allergic disorders. This device is designed for use in clinical laboratories.

9. Summary of Testing

The OPTIGEN Allergen-Specific IgE assay is a modification of the CLA Allergen-Specific assay. The new device is comprised of three molded parts with a polystyrene solid phase, a serum volume requirement of < 500 micro liters for up to 36 results, reduced number of reagents, a stability of 24 months and a single day assay.

The product modifications consist of:

1. Several design changes not affecting the indications for use or the fundamental scientific technology.
2. Several labeling changes, not affecting the indications for use, have been added for label clarity, to enhance the product use and to reflect the design modifications.
3. The product name has been changed from the CLA Allergen-Specific IgE Assay System to the OPTIGEN Allergen-Specific IgE Assay System.
4. Addition of new control sera to be used by customers in verifying allergen performance.
5. The expiration dating has been extended to 24 months.

Three-performance comparison studies were done in France, Germany and the USA with the OPTIGEN Universal Panel 20, using the OPTIGEN Allergen-Specific IgE Assay System, tested in parallel with Pharmacia CAP system Specific IgE Assay, a commercially available assay. The three studies included a total of 1753 determination points for the 20 allergens in the panel. The comparison data shows that determination of specific IgE to 20 allergens with the OPTIGEN Allergen-Specific IgE Assay is substantially equivalent to Pharmacia CAP Specific IgE Assay, the legally marketed predicate device.

Hitachi OPTIGEN Allergen Specific IgE vs. Pharmacia CAP Specific IgE Assay for 20 allergens

OPTIGEN vs. PHARMACIA CAP

Hitachi Class	0	1	2	3	4,5 &6
4	0	3	86	133	98
3	7	3	61	33	12
2	20	19	83	37	9
1	50	20	56	21	4
0	917	45	30	6	0

PHARMACIA CAP CLASS

TOTAL DATA POINTS: 1753

		Pharmacia CAP		
Hitachi OPTIGEN		+	-	Total
	+	678	77	755
	-	81	917	998
Total		759	994	1753

Positive percent agreement: 89.3% (678/759)
Negative percent agreement: 92.2% (917/994)
Overall agreement: 91% (1595/1753)

10. Conclusion

The comparison data shows that determination of specific IgE with the OPTIGEN® Allergen-Specific IgE Assay System has clinical performance profile that is substantially equivalent to Pharmacia CAP Specific IgE Assay, the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Hitachi Chemical Diagnostics
c/o Emi Zychlinsky, Ph.D
Vice President, R&D
630 Clyde Ct.
Mountain View, CA 94043

JAN 23 2006

Re: k051677
Trade/Device Name: OPTIGEN® Allergen-Specific IgE assay System
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: Class II
Product Code: DHB, DGC
Dated: June 21, 2005
Received: June 29, 2005

Dear Dr. Zychlinsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, PH.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K051677

Name: OPTIGEN Allergen-Specific IgE Assay System

Indications for Use:

The OPTIGEN assay is an *in vitro* test, which provides a semi quantitative measurement of circulating allergen specific IgE antibodies in human serum. The OPTIGEN assay is intended to assist in the clinical diagnosis of IgE-mediated allergic disorders. This device is designed for use in clinical laboratories.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic **Device**
Evaluation and Safety

510(k) K051677